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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,783	04/26/2002	Satoshi Mori	SAE-005	7671

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,783

Applicant(s)

MORI ET AL.

Examiner

Medina A Ibrahim

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5 and 7-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5 and 7-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 01/13/05 in reply to the Office action of 08/26/04 has been entered. Claims 1, 3, 5, and 7-10 have been amended. Claims 2, 4 and 6 have been cancelled. Claim 12 has been added. Therefore, claims 1, 3, 5, 7-12 are pending and are examined.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment. The 35 USC 102(a) rejection to the claims as being anticipated by Satoshi et al (EP0860499 A2) has been withdrawn in favor of 35 USC 103 rejection, since the claims are amended to recite a specific plasmid vector.

Claim Objections

At claims 1 and 8-9, "an" in parts (A) and (B) before " amino acid sequence of SEQ ID NO: " should be changed to ---the--- because it refers to specific sequence. Also, ---Celsius--- should be inserted after "65 degrees". Also, "(A)" and "(B)" should be changed to ---(a) and ---(b)---, respectively, in each occurrence.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5, and 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "using" without any active, positive steps delimiting how this use is actually practiced. The claim does not set forth any steps involved in the use. Therefore, it is unclear what method/process step Applicant is intending to encompass. Clarification is required to more clearly define the metes and bounds of the claim. Dependent claims 3, 5, and 7-12 are included in the rejection.

Claim 3 is indefinite because it is unclear if the promoter is in addition to the 35S promoters already present in the vector recited in claim 1.

Claim 7 recites "any one of claims 1 to 3". The claim is indefinite for depending upon cancelled claim 2. Dependent claims 10-12 are included in the rejection.

Written Description

Claims 1, 3, 5 and 7-12 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth in the last Office action of 08/26/04. Applicant's arguments filed in 01/13/05 have been considered but are not deemed persuasive.

The claims as amended are broadly drawn to a method of producing transgenic gramineae having iron deficiency by transforming the plant with a polynucleotide encoding nicotianamine amino transferase (NAAT) and that hybridizes to a polynucleotide encoding SEQ ID NO: 1 or 2 under the conditions recited in the claims, and said polynucleotide includes a barley naat gene. The claims are also drawn to

Art Unit: 1638

transgenic gramineae plants with iron deficiency resistance, and a method of growing said plants and seed thereof in iron deficient field to produce crops.

Applicant asserts that the claims as amended meet the written description requirement. This assertion is incorrect because the specification does not describe a method other than that employs a polynucleotide encoding SEQ ID NO: 1 or 2 as discussed in the last Office action. The specification does not describe a representative number of polynucleotides that fall within the scope of claimed genus, and a review of the literature does not indicate that these polynucleotides would be well known to an artisan. Given this lack of description of a representative number of polynucleotides encoding NAAT required for the production of transgenic Gramineae/cells/seed having resistance to iron deficiency, the claimed invention is not adequately described. Consequently, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that one skilled in the art would recognize that Applicants are in possession of the invention as broadly claimed. Therefore, for the reasons discussed above and in the last Office action, the rejection is maintained. See the *University of Rochester v. G.D. Searle & Co., Inc.*, (U.S. District Court, Western District of New York, Decision and Order No. 00-CV-6161L,) decided 05 March 2003, at page 8, bottom paragraph, cited in the last Office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1638

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5 and 7-12 are rejected under 35 U.S.C. 103(a) as being obvious over by Satoshi et al (EP0860499 A2, Applicant's IDS) in view of Hiei et al (US 5, 591, 616).

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

The claims as amended are broadly drawn to a method of producing transgenic gramineae having iron deficiency by transforming the plant using specific vector

Art Unit: 1638

comprising a polynucleotide encoding nicotianamine amino transferase and that hybridizes to a polynucleotide encoding SEQ ID NO: 1 or 2 under the conditions recited in the claims, and said method wherein the polynucleotide is the barley naat gene. The claims are also drawn to transgenic gramineae plants with iron deficiency resistance, and a method of growing said plants and seed thereof in iron deficient field to produce crops.

Satoshi et al teach methods of isolating and using a gene from barley encoding NAAT having 100% sequence identity to Applicant's SEQ ID NO: 1 or 2 for transformation of a gramineae plant. The method comprises introducing into the plant an expression vector comprising the gene operably linked to CaMV35S promoter. On page 4, lines 44-58, the cited reference teaches that expression of NAAT gene in the plant is induced by iron deficiency conditions and induces increased uptake of insoluble iron from the soil by the plant. The cited reference further teaches that the transformed gramineae having resistance to iron-deficiency, cells and seed thereof expressing NAAT for use in iron-deficiency field (see at least the Abstract). While Satoshi et al teach construction of plasmid vectors (comprising the barley NAAT gene operably linked with the 35S promoter, NOS terminator, and a selectable marker) for transformation of gramineae plant and plant cells, Satoshi et al do not explicitly use a vector *pIG121Hm* or *pBGR Z*.

Hiei et al teach the vector *pIG121Hm*, and a method of transforming a Gramineae with said vector.

Art Unit: 1638

Therefore, it would have been obvious to one of ordinary skill in the art at the time this invention is made to use the method of transforming gramineae with the barley NAAT polynucleotide using a vector to produce gramineae plant and seed with resistance to iron deficiency as taught by Satoshi et al. One would have been motivated to do so because majority of important cereal crops such as rice are known to be susceptible to iron deficiency. One can also modify the method by Satoshi et al by incorporating a plasmid vectors known in the art such as *pIG121Hm* as taught by Hiei et al, without any unexpected results. Therefore, the invention as whole was a prima facie obvious.

Contrary to Applicant's arguments of 01/13/05, transformation of Gramineae using the vector *pIG121Hm* was well known in the art. At the time Applicant's invention was made, one of ordinary skill in the art could construct a plant transformation plasmid vector comprising a desired gene without encountering any difficulties.

Remarks

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

Art Unit: 1638

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/16/05
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